## NATIONAL GUI DELI NE CLEARI NGHOUSE™ (NGC) GUI DELI NE SYNTHESI S

## TOBACCO USE CESSATION AND PREVENTION

#### Guidelines

- 1. University of Michigan Health System (UMHS). <u>Smoking cessation.</u> Ann Arbor (Michigan): University of Michigan Health System, 2001. 9 p. [1 reference]
- 2. Singapore Ministry of Health (MOH). <u>Smoking cessation.</u> Singapore: Singapore Ministry of Health; 2002 Apr. 33 p. [82 references]
- 3. New Zealand Guidelines Group (NZGG). <u>Guidelines for smoking cessation:</u> revised 2002. Wellington (New Zealand): National Advisory Committee on Health and Disability (National Health Committee); 2002 May. 33 p. [42 references]
- U.S. Preventive Services Task Force (USPSTF). <u>Counseling to prevent tobaccouse and tobacco-caused disease</u>: <u>recommendation statement</u>. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2003 Nov. 13 p. [22 references]
- 5. Veterans Affairs, Department of Defense (VA/DoD). <u>VA/DoD clinical practice</u> guideline for the management of tobacco use. Washington (DC): Department of Veteran Affairs; 2004 Jun. 81 p.

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#### INTRODUCTION:

A direct comparison of UMHS, Singapore MOH, NZGG, USPSTF, and VA/DoD recommendations for tobacco use cessation and prevention is provided in the tables below. <u>Table 1</u> provides the scope of the guidelines, <u>Table 2</u> compares the major recommendations, and <u>Table 3</u> compares the potential benefits and harms of implementing the recommendations. Definitions for the levels of evidence used to support the guideline recommendations are given in <u>Table 4</u>; references supporting the Singapore MOH recommendations are also provided in this table.

The comparison in <u>Table 2</u> is restricted to recommendations for interventions to be carried out by physicians and/or other health care professionals. The NZGG guideline also contains many recommendations specific to the Maori population of New Zealand. The user is directed to the individual guidelines for information on these recommendations.

Following the tables and discussion of content comparison, the areas of agreement and differences among the guidelines are identified. In general, the timing of guideline development with respect to available data is an important factor to consider when evaluating areas of differences among the guidelines. Interpretation of available data is also considered.

#### Related Guidelines

- Centers for Disease Control and Prevention/Task Force on Community Preventive Services. <u>Strategies for reducing exposure to environmental</u> <u>tobacco smoke, increasing tobacco-use cessation, and reducing initiation in</u> <u>communities and health-care systems</u>. Am J Prev Med 2001 Feb; 20(2 Suppl): 10-5 [21 references].
- Registered Nurses Association of Ontario (RNAO). <u>Integrating smoking cessation into daily nursing practice</u>. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2003 Oct. 80 p. [59 references].
- New York State Department of Health. <u>Smoking cessation in HIV-infected patients</u>. New York (NY): New York State Department of Health; 2005 Jun. 8 p. [17 references].

Listed below are common abbreviations used within the tables and discussions:

- AHRQ, Agency for Healthcare Research and Quality
- DoD, Department of Defense
- FDA, Food and Drug Administration
- MOH, Ministry of Health (Singapore)
- NRT, Nicotine replacement therapy
- NZGG, New Zealand Guideline Group
- UMHS, University of Michigan Health System
- U.S., United States
- USPSTF, United States Preventive Services Task Force
- VA, Veterans Affairs

TABLE 1: SCOPE		
	Objectives	
UMHS (2001)	To provide a systematic framework for care providers to assist patients in smoking cessation	
SINGAPORE MOH (2002)	To provide recommendations for smoking abstinence	
NZGG (2002)	<ul> <li>To increase the quit rate among smokers seen by health workers</li> <li>Specific Aims</li> <li>To reinforce the importance of smoking as a preventable adverse health factor</li> <li>To promote the integration of smoking cessation interventions into routine clinical care throughout the health system</li> <li>To improve the information and support given people who want to stop smoking</li> <li>To ensure all health workers feel confident in the advice they give and the resources available to support smoking cessation</li> <li>To promote the use of nicotine replacement therapy, as an adjunct to ongoing support for people attempting to quit</li> </ul>	
USPSTF (2003)	<ul> <li>To summarize the USPSTF recommendations on counseling to prevent tobacco use and tobacco-caused disease and the supporting scientific evidence</li> <li>To update the 1996 recommendations contained in the Guide to Clinical Preventive Services, Second Edition</li> </ul>	
VA/DoD (2004)	<ul> <li>To assist providers and tobacco specialists in delivering more effective treatments that reduce the prevalence of tobacco use among the beneficiaries of the Veterans Health Administration and the Department of Defense</li> <li>To assist patients to quit using tobacco and, therefore, improve clinical outcomes</li> </ul>	

Target Population	
raiget Fopulation	
UMHS (2001)	<ul> <li>United States</li> <li>The guideline focuses primarily on adult smokers; adolescents are addressed in the context of special populations.</li> </ul>
SINGAPORE MOH (2002)	<ul> <li>Singapore</li> <li>Adult smokers (children and adolescent tobacco users are not addressed in this guideline)</li> </ul>
NZGG (2002)	<ul> <li>New Zealand</li> <li>Smokers in New Zealand, including pregnant women, children and adolescents, and native Maori people</li> </ul>
USPSTF (2003)	<ul> <li>United States</li> <li>General population, including adults, pregnant women, and children, seen in primary care settings</li> </ul>
VA/DoD (2004)	<ul> <li>United States</li> <li>Any person (age greater than 12 years) who is eligible for care in the Veterans Health Administration or the Department of Defense health care delivery system (including adults, and students in elementary and middle schools)</li> </ul>
"	Intended Users
UMHS (2001)	Health Care Providers, Physicians
SINGAPORE MOH (2002)	Advanced Practice Nurses, Dentists, Health Care Providers, Hospitals, Nurses, Pharmacists, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians
NZGG (2002)	Advanced Practice Nurses, Allied Health Personnel, Dentists, Health Care Providers, Nurses, Pharmacists, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians, Public Health Departments, Respiratory Care Practitioners, Substance Use Disorders Treatment Providers
USPSTF (2003)	Advanced Practice Nurses, Nurses, Physician Assistants, Physicians, Public Health Departments

VA/DoD (2004)	Advanced Practice Nurses, Allied Health Personnel, Physician Assistants, Physicians, Psychologists/Non-physician Behavioral Health Clinicians, Students
	Interventions And Practices Considered
UMHS (2001)	Screening to identify and document tobacco use status
, ,	Counseling and patient education, including:
	<ul> <li>"5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)</li> <li>4 R's (relevance, risk, rewards, repetition) motivational intervention for users not ready to quit</li> </ul>
	Pharmacotherapy:
	<ul> <li>First-line: <ul> <li>Bupropion SR (sustained-release bupropion)</li> <li>Nicotine gum</li> <li>Nicotine inhaler</li> <li>Nicotine nasal spray</li> <li>Nicotine patch</li> </ul> </li> <li>Second-line: <ul> <li>Clonidine</li> <li>Nortriptyline</li> </ul> </li> <li>Combination Therapy</li> </ul>
	Follow-up to prevent relapse
	Tailoring of treatments to special populations
	Advice on weight gain after smoking cessation
	Advice on non-cigarette tobacco products
SINGAPORE	Screening to identify and document tobacco use status
MOH (2002)	Counseling and patient education, including:
	<ul> <li>"5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)</li> <li>5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)</li> </ul>
	Pharmacotherapy:
	Nicotine replacement therapy (NRT), including nicotine patch (available as 24-hour and 16-hour patches) or nicotine

	<ul> <li>inhaler</li> <li>Bupropion hydrochloride slow release (SR)</li> <li>Other drugs, such as clonidine and nortriptyline, as secondline therapy</li> <li>Combination therapy</li> <li>Drug therapy during pregnancy</li> </ul> Counseling and behavior therapy used in conjunction with pharmacotherapy
NZGG (2002)	Screening to identify and document tobacco use status  Counseling and patient education, including:  • "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)  • 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)  • Telephone quitlines and Aukati Kai Paipa (smoking cessation service)  Pharmacotherapy:  • First-line:  • Nicotine replacement therapy (NRT), including nicotine gum, nicotine nasal spray, nicotine patch, nicotine inhaler  • Second line:  • Bupropion  • Nortriptyline  • Combination therapy  Special considerations for high-risk groups:  • Pregnant women  • Children and adolescents  • Other high-risk populations within New Zealand, including Maori  Smoking cessation training for health professionals
USPSTF (2003)	Screening to identify and document tobacco use status  Counseling and patient education, including:  • "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)  • 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)  • Telephone quitlines

- Augmented pregnancy-tailored counseling
- Self-help materials

## Pharmacotherapy, including:

- Nicotine replacement therapy (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray)
- Sustained-release bupropion
- Clonidine
- Nortriptyline
- Combination therapy

## VA/DoD (2004)

Screening to identify and document tobacco use status

Counseling and patient education, including:

- "5-A" behavioral counseling framework (ask, advise, assess, assist, arrange)
- 5 R's used to treat tobacco use (relevance, risk, rewards, roadblocks, repetition)
- Telephone guit lines
- Self-help materials

#### Pharmacotherapy:

- Firstline NRT:
  - Transdermal delivery system (patches, e.g., Nicoderm CQ)
  - Polacrilex resin (gum)
  - Polacrilex resin (lozenge)
  - Nasal spray (Nicotrol NS)
  - Oral vapor inhaler (Nicotrol Inhaler)
- Non-nicotine replacement products:
  - First line: Bupropion SR (sustained release) and bupropion IR (immediate release)
  - Second Line: Clonidine and nortriptyline
- Combination Therapy

## Prevention strategies

- Relapse prevention treatment (counseling and pharmacologic)
- Encouraging children and adolescents to stay abstinent

Tailoring of treatments to special populations (children/adolescents, pregnant women, hospitalized patients, older individuals, military personnel, psychiatric/mental health patients)

TABLE 2: RECOMMENDATIONS FOR TOBACCO USE CESSATION AND PREVENTION		
	SCREENING AND ASSESSMENT	
	Screening for Tobacco Use	
UMHS (2001)	Ask all patients about smoking status and assess smoker's readiness to quit.	
	Smoking status should be documented in the medical record. Techniques to remind the physician of a patient's smoking status include smoking status stickers, listing tobacco use on active problem list of tobacco status as part of vital signs.	
SINGAPORE MOH (2002)	All patients should be asked if they use tobacco and should have their tobacco use status documented on a regular basis. Clinicians and health care delivery systems should institutionalise the consistent identification, documentation, and treatment of every tobacco user seen in a health care setting (Chang, Zimmerman, & Beck, 1995; National Cancer Institute, 1994; Ockene, 1987; Pederson, Baskersville, & Wanklin, 1982; Robinson, Laurent, & Little, 1995; Yarnall et al., 1998). (Grade A, Level Ia, Ib)	
	For example: Expand the vital signs to include tobacco use. Place tobacco use stickers on patient records. Indicate tobacco use status in electronic medical records or computer reminder systems.	
NZGG (2002)	The smoking status of every adult should be identified and prominently documented in the medical record. For current smokers and those who have quit in the past year, smoking status should be updated at each visit.	
	Place a smoking status and/or second-hand smoke sticker on the master problem list, or electronically document in computerised notes.	
	For identified smokers and recent quitters (within one year), update smoking status at each visit.	
USPSTF (2003)	The USPSTF strongly recommends that clinicians screen all adults for tobacco use and provide tobacco cessation interventions for those who use tobacco products (A recommendation).	
	Clinics that implement screening systems designed to regularly identify and document a patient's tobacco use status increased	

	their rates of clinician intervention, although there is limited evidence for the impact of screening systems on tobacco cessation rates.
VA/DoD (2004)	Patients should be asked about tobacco use at most visits, as repeated screening increases rates of clinical intervention. [A]
	<ul> <li>Screening for tobacco use in primary care should occur at least three times/year. [Expert Consensus]</li> <li>Screening for tobacco use by other specialties or disciplines should be done at least once per year. [Expert Consensus]</li> <li>Screening adolescents should include assessment of environmental tobacco exposure.</li> </ul>
	Background. In order to assess tobacco use status, all patients should be asked about their use of tobacco (including the use of tobacco in any form) upon visiting any provider. This may be accomplished when the patient's vital signs are taken. The tobacco use status should be noted in the patient's record. If the medical record indicates that the patient has never used tobacco or has not used it for many years, repeated assessment is not necessary.
	Willingness to Quit and Motivational Strategies
UMHS (2001)	Assess whether the patient is "ready to attempt to quit."
	If "yes," set a quit date, assist by providing personalized advice, pharmacologic therapy as appropriate, and information on community programs, and arrange follow-up.
	If "no," offer motivational interventions using the 4 "R's"
	<ul> <li>Relevance: impact of smoking on current health/illness and/or on children and others in household; economic costs of tobacco use</li> </ul>
	<ul> <li>Risks: potential negative consequences of smoking</li> <li>Rewards: improved health, improved taste, money saved</li> <li>Repeat above strategies with unmotivated patients at every visit</li> </ul>
SINGAPORE MOH (2002)	Once a tobacco user is identified and advised to quit, the health care practitioner should assess the patient's willingness to quit at this time:
	<ul> <li>Patients willing to try to quit tobacco use should be provided treatments identified as effective in this set of guidelines.</li> <li>Patients unwilling to try to quit tobacco use should be provided a brief intervention designed to increase their</li> </ul>

motivation to quit as described in this set of guidelines (e.g., the 5 R's, relevance, risks, rewards, roadblocks, and repetition). (Grade C, Level IV)

#### Motivational Intervention

Patients unwilling to make a quit attempt may lack information about the harmful effects of tobacco, may lack the required financial resources, may have fears or concerns about quitting, or may be demoralised because of previous failed efforts. Such patients may respond to a motivational intervention such as those built around the 5R's: relevance, risks, rewards, roadblocks, and repetition. Motivational interventions are more likely to succeed if the clinician is empathetic, allows patients to make their own choices, does not argue with the patients, and encourages them to believe that they can quit by helping them identify previous successes in their attempts to quit.

## NZGG (2002)

Determine the willingness of smokers to make a quit attempt by asking every smoker how they feel about their smoking.

The purpose of determining a person's willingness to quit is to enable the most appropriate and beneficial assistance to facilitate smoking cessation.

Smoking cessation is a process occurring over time. A commonly accepted model is Prochaska & DiClemente's "stages of change," in which smokers are seen as moving through a series of stages:

Precontemplative (not considering quitting)

TO

Contemplative (planning to quit in the next six months)

TO

Action (ready to quit soon)

TO

• Maintenance/relapse

If the person clearly states he/she is unwilling to make a quit attempt at this time, provide relevant information and assure them that their health care team is available to help when ready.

Time permitting, explore barriers to considering quitting and provide motivational interventions as specified in the 5 R's

	(relevance, risks, rewards, roadblocks, and repetition)
USPSTF (2003)	Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to quit and to overcome common barriers to quitting and providing social support within and outside of treatment.  Common practices that complement this framework include
	motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quit lines" have also been found to be an effective adjunct to counseling or medical therapy.
VA/DoD (2004)	Assess Willingness to Quit
(2004)	Tobacco users should be assessed for willingness to quit at every visit. [C]
	Willingness to quit should be assessed at least three times/year. [Expert Consensus]
	Background. Tobacco users should be given advice appropriate to their level of interest in quitting. Approximately 70 percent of tobacco users want to quit. The patient's level of interest will determine subsequent steps to be taken. By knowing the person's stage of willingness to quit tobacco use, the health care provider can decide whether to provide motivational material to quit tobacco use or, alternatively, specific instructions to help the person quit.
	Promote Motivation to Quit
	Tobacco users who are not willing to quit at this time should receive brief, non-judgmental motivational counseling designed to increase their motivation to quit, to include discussion about [Expert Consensus]:
	<ul> <li>Relevance: connection between tobacco use and current symptoms, disease, and medical history</li> <li>Risks: risks of continued tobacco use and tailor the message to individual risk/relevance of cardiovascular disease or exacerbation of preexisting disease</li> <li>Rewards: potential benefits for quitting tobacco use to their medical, financial, and psychosocial well-being</li> <li>Roadblocks: barriers to quitting and discuss options and strategies to address patient's barriers</li> <li>Repetition: Reassess willingness to quit at subsequent visits;</li> </ul>

	repeat intervention for unmotivated patients at every visit.
	Use of motivational intervention should be considered. This technique has been shown to be beneficial in motivating and changing behaviors of individuals with other substance use dependencies, including some evidence in cessation of smoking. [B]
	TREATMENT STRUCTURE AND INTENSITY
	Advise Tobacco Users to Quit
UMHS (2001)	Advise all smokers to seriously consider making a quit attempt using a clear and personalized message.
SINGAPORE MOH (2002)	All clinicians should strongly advise every patient who smokes to quit ("Practice guideline," American Psychiatric Association, 1996; Orleans, 1993; US Department of Health and Human Services, 1988). (Grade A, Level Ia)
NZGG (2002)	Provide brief cessation messages at nearly every encounter. These messages should be: clear, strong and personalized; supportive; and non-confrontational.
USPSTF (2003)	Advise smokers to quit through clear personalized messages.
VA/DoD (2004)	Tobacco users should be advised to quit at every visit because there is a dose-response relationship between number of contacts and abstinence. [A]
	Background. Every health care team member should urge every tobacco user to quit. Repeated messages on the importance of quitting made over time have an accumulated effect on encouraging patients to quit.
	Intensity of Clinical Interventions
UMHS (2001)	Advice as brief as 3 minutes is effective in smoking cessation [C]. In addition to clinician counseling in the office, intensive counseling (frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates. However, participation in intensive counseling is based largely on patients' motivation to quit and ability to pay [C].
SINGAPORE MOH (2002)	Brief tobacco dependence treatment is effective and every patient who uses tobacco should be offered at least brief

	treatment. (Grade A, Level IIa)
	There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. (Grade A, Levels Ia, Ib, IIa)
NZGG (2002)	Brief, repetitive, consistent, positive reminders to quit from multiple providers (or reinforcement of a recent quit attempt) double success rates.
USPSTF (2003)	Brief tobacco cessation counseling interventions, including screening, brief counseling (3 minutes or less), and/or pharmacotherapy, have proven to increase tobacco abstinence rates, although there is a dose-response relationship between quit rates and the intensity of counseling. Effective interventions may be delivered by a variety of primary care clinicians.
VA/DoD (2004)	<ul> <li>Physicians should strongly advise tobacco users to quit, as physician advice increases abstinence rates. [A]</li> <li>Health care team members should strongly advise all tobacco users to quit. [B]</li> </ul>
	Background. This message should be delivered in the brief "advice" format such that it is clear, (e.g., "I think it is important for you to quit tobacco use now and I can help you."), concise, strong, (e.g., "As your clinician I want you to know that quitting tobacco use is the most important thing you could do to protect your health.") and personalized (e.g., "Quitting your tobacco use will help improve your [health symptom or specific disease]").
Follow-	-up Assessment and Procedures (Prevention of Relapse)
UMHS (2001)	Arrange follow-up either with phone call or office visit. Follow-up contact should occur soon after the quit date, preferably during the first week [C]. Extending treatment contacts over a number of weeks appears to increase cessation rates [D]. Further follow-up as needed.
	For abstinent patients, prevent relapse by congratulating successes and reinforcing reasons for quitting. Assess any difficulties with pharmacologic therapy. Patients who relapse should be considered for more intensive counseling or should have their pharmacotherapy reassessed and should be advised to make another quit attempt.
SINGAPORE MOH (2002)	When clinicians encounter a patient who has quit smoking recently, they should reinforce the patient's decision to quit, review the benefits of quitting, and assist the patient in resolving

any residual problems arising from quitting.

Although most relapses occur early in the quitting process, some relapses occur months or even years after the quit date. Therefore, clinicians should engage in relapse prevention interventions even with former tobacco users who no longer consider themselves actively engaged in the quitting process. (Grade A, Levels Ia & Ib)

## NZGG (2002)

Arrange appropriate follow-up for all smokers who are:

- not considering quitting
- planning to guit but not soon
- ready to quit within the next month
- and those who have recently quit as relapse prevention or for those who have recently relapsed.

Arrange follow-up (in person or by phone) with smokers who are ready to quit:

- first follow-up within the first week
- second follow-up within the first month
- reinforce staying quit during visits in the first year postcessation

Follow-up by nurses, community workers, and other health workers, as well as doctors, can be effective. Letters/phone calls may be more cost-effective than follow-up visits at the clinic.

Actions during follow-up contact — congratulate success. If smoking has occurred, review circumstances and elicit recommitment to total abstinence. Remind patient that a lapse can be used as a learning experience. Identify problems already encountered and anticipate challenges in the immediate future. Assess pharmacotherapy use and problems.

## Relapse Prevention

- Reinforce the importance of permanent cessation.
- Health professionals should be aware that personal circumstances may make it difficult for people to stay quit.
- Make people aware of major triggers, for example, stress and alcohol.
- Use open-ended questions to identify what precipitated or is precipitating the relapse and encourage active discussion to identify strategies to overcome this.

## Recently Relapsed

Ask what precipitated the relapse, and help identify

strategies to overcome this in the future. Reaffirm person's ability to quit. Encourage them to set another quit date. Provide them with the free QUITLINE number (0800 778 778 in New Zealand) or other smoking cessation support. USPSTF Arrange follow-up and support (after assisting in quitting). (2003)VA/DoD Arrange Follow-up (2004)Tobacco users who receive a tobacco cessation intervention should be scheduled for ongoing follow-up for abstinence. [B] Follow-up should be documented and should: Establish contact with the tobacco user 1 to 2 weeks after quitting date to assess abstinence [B] Assess effectiveness of pharmacotherapy and appropriate use [Expert Consensus] Assess for abstinence at the completion of the treatment and during subsequent clinical contact for the duration of at least 6 months [Expert Consensus] Provide relapse prevention to tobacco users who remain abstinent Tobacco users who relapse should be assessed for willingness to make another guit attempt and offered repeated interventions. [B] Tobacco users should be tracked to increase the systematic delivery of interventions for tobacco cessation and increase the likelihood of long-term abstinence. [B] Background. Tobacco dependence is a chronic disease that often requires repeated interventions. Tobacco addiction is a chronic disorder that carries with it the vulnerability to relapse persisting for weeks, months, and perhaps even years. Therefore, consistent follow-up is necessary to ensure optimal care. Initiate/Reinforce Relapse Prevention Relapse prevention should be addressed with every former tobacco user. [Expert Consensus] Providers should address individual, environmental, and biopsychosocial factors associated with relapse. [Expert Consensus1 Providers should address weight gain after guitting, as tobacco use cessation is often followed by weight gain.

- Consider bupropion SR (sustained release) or NRT, in particular, nicotine gum, which have been shown to delay weight gain after quitting.
- Patients with multiple relapses or who are having trouble in a current quit attempt in a clinical setting should be directed to more intense counseling programs or medication should be adjusted. [B]

Background. Tobacco use is characterized as a chronic relapsing disorder due to the high number of relapses after a single quit attempt. Studies have documented that smokers may make between 3 and 7 serious quit attempts before successfully quitting. Relapse frequently occurs within a few hours or up to 3 months after quitting, and may even occur after a year or more of abstinence. Addressing the issue of relapse before it occurs and identifying risk factors has been helpful in devising coping strategies to help the tobacco user to quit and prepare them to accept relapse as a learning experience and not a failure.

## Assess Risk for Relapse

- Tobacco users who have been abstinent for less than three months should be assessed for relapse. [B]
- Tobacco users attempting to quit should be screened for a history of depression or a presentation of depressive symptoms predating the quit attempt as these factors strongly predict relapse. [B]
- Psychosocial and environmental risk factors for relapse should be assessed to include stress, depression, withdrawal symptoms, previous quit attempts, close presence of other tobacco users, history of substance use disorder, and/or other risky behaviors. [C]
- Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. [C]

#### Relapse

- Patient who responded to therapy and successfully quit the use of tobacco and then relapsed should be treated in same manner as the initial therapy.
- Insufficient evidence exists to recommend the use of extended pharmacotherapy for relapse prevention. [1]
- Consider referral for intensive behavioral modification counseling for tobacco users with multiple relapses. [Expert Consensus]

#### TREATMENT ELEMENTS

Counseling and Behavioral Therapies

## UMHS (2001)

Help the patient with a quit plan:

- Set a quit date and record this on patient's chart. Ask the patient to mark his/her calendar. Quit date abstinence is a strong predictor of long-term success [C].
- Patient should inform family, friends, co-workers of quit plan and request support.
- Have patient remove cigarettes from home, car, and workplace environments.
- Anticipate challenges, particularly during the first critical few weeks (i.e., nicotine withdrawal symptoms).

Consider referral to intensive counseling (multi-session, group or individual). Referral considerations include:

- Multiple, unsuccessful quit attempts initiated by brief intervention
- Increased need for skill building (coping strategies/problem solving), social support, and relapse prevention
- Psychiatric cofactors such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse

Give advice on successful quitting.

Provide supplemental educational materials.

## SINGAPORE MOH (2002)

Quit plan:

Prepare the patient to stop smoking by setting a quit date. Inform family, friends and colleagues about intention to quit and request understanding and support. Anticipate challenges to the planned quit attempt, particularly during the critical first few weeks. Remove tobacco products from the environment. Help patient choose from several options to stop.

Options to stop smoking:

- Patient stops on his own with minimal assistance
- Patient stops with your assistance and follow up.
- Patient is referred to a dedicated smoking cessation programme

## NZGG (2002)

Help them develop a quit plan:

- Set a quit date.
- Tell family, friends and co-workers about quitting and request understanding and support.
- Anticipate challenges to planned guit attempt.

Remove tobacco product from the environment. Provide practical counselling (problem solving/skills training): Total abstinence is essential. "Not even a single puff after the quit date." Identify what helped and what hurt in previous quit attempts. Discuss challenges/triggers and how patient will successfully overcome them. Since alcohol can trigger relapse, the patient should consider limiting/abstaining from alcohol while quitting. Quitting is more difficult when there is another smoker in the household. Patients should encourage housemates to guit with them or not smoke in their presence. Provide support and assist patient to gain support in their environment. If a patient is a member of a special high-risk population (for example adolescent, pregnant smoker) consider providing additional information and support. **USPSTF** Helpful aspects of counseling include providing problem-solving guidance for smokers to develop a plan to guit and to overcome (2003)common barriers to quitting and providing social support within and outside of treatment. Common practices that complement this framework include motivational interviewing, the 5 R's used to treat tobacco use (relevance, risks, rewards, roadblocks, repetition), assessing readiness to change, and more intensive counseling and/or referrals for quitters needing extra help. Telephone "quitlines" have also been found to be an effective adjunct to counseling or medical therapy. VA/DoD Initiate Counseling (2004)Counseling in the Clinic Tobacco users who are willing to quit should receive some form of counseling. There is a dose-response relationship in counseling and rate of abstinence. [A] Minimal counseling (lasting [A] Intensive counseling (>10 minutes) increases abstinence rates. [A] Multiple counseling sessions increase abstinence rates. [A] Effective counseling can be delivered in multiple formats (e.g., group counseling, proactive telephone counseling, and individual

counseling) and may be more effective when combined. [A]

Counseling should be provided by a variety of clinician types (physicians or nonphysician clinicians, such as nurses, dentists, dental hygienists, psychologists, pharmacists, and health educators) to increase quit rates. [A]

All patients who are willing to quit should have access to intensive counseling (Quitlines or intensive cessation program).

#### Quitlines

Tobacco users who are willing to quit may receive counseling via telephone Quitlines, as proactive telephone counseling has been demonstrated to be effective. Pharmacotherapy still needs to be coordinated by the primary care provider. [A]

Background. There is strong evidence that behavioral interventions work. More intense interventions, as defined by face-to-face contact, using a multidisciplinary approach and multiple formats, result in better cessation outcomes. However, even brief counseling increases overall abstinence rates. Effective counseling can also be provided by a wide variety of health care professionals, in addition to the patient's primary care physician. Tobacco use counseling and treatment can be provided in a variety of settings. It is crucial that the provider ensures that the tobacco user receives counseling and medication to assist him/her in quitting, regardless of the setting. Counseling tobacco users should start with having the patient set a guit date.

Counseling and behavioral tobacco use cessation interventions should include: (1) providing practical counseling (problemsolving skills/skills training), (2) providing social support as part of treatment, and (3) helping tobacco users obtain social support outside of treatment. These three types of counseling and behavior therapies result in higher abstinence rates. Proactive telephone counseling, such as that provided by a Quitline, is another effective option for providing counseling to tobacco users.

Note: Aversive smoking interventions (rapid smoking, rapid puffing, other aversive smoking techniques) increase abstinence rates and may be used with smokers who desire such treatment or who have been unsuccessful using other interventions. [B] Although aversive smoking has been demonstrated to be effective, it is rarely used due to the availability of medication.

	Adjunctive Pharmacotherapy
UMHS	Both nicotine replacement therapy (NRT) and bupropion

### (2001)

hydrochloride (Zyban) have been shown to significantly improve cessation rates [A]. Therefore, pharmacologic therapy should be recommended to all patients except in the presence of special circumstances (see <u>Considerations in Special Populations</u> below). At the time of publication of the 2001 UMHS guideline, bupropion hydrochloride was the only non-nicotine product with FDA approval for smoking cessation.

Non-FDA approved agents with potential benefit in smoking cessation include nortriptyline and clonidine. These drugs may best be used as second-line agents when patients cannot take or do not wish to take either NRT or bupropion [D].

## Combination Therapy

Given the additional cost of dual therapies (e.g., patch plus gum; patch plus inhaler; patch plus nasal spray) and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts.

## SINGAPORE MOH (2002)

NRT is effective and safe for smoking cessation (Abelin et al., 1989; Bohadana et al., 2000; Dale et al., 1995; Hjalmarson et al., 1997; Hurt et al., 1994; Lewis et al., 1998; Silagy et al., 1994; Silagy et al., 2000; Tonnesen et al., 1993). (Grade A, Level Ia)

At the time of the publication of this 2002 guideline, available NRT products in Singapore were the nicotine patch and inhaler.

There is no difference in efficacy between various forms of nicotine replacement (Gourlay et al., 1995; Hjalmarson et al., 1997; Hurt et al., 1994; Sachs, Sawe, & Leischow, 1993; Silagy et al., 2000). (Grade A, Level Ib)

Bupropion Slow-Release (SR) is safe and effective for smoking cessation. (Grade A, Level Ib)

Although current data suggest that clonidine and nortryptiline may be useful in smoking cessation, they should be used only when first line therapies fail. They have significant side effects and should be used only by those who are well versed in their use. (Grade C, Level IV)

#### Combination Therapy

Studies with combination NRT suggest improvement in efficacy over single NRT over a short-term period (Bohadana et al., 2000; Blondal et al., 1999). However, results over medium-term (1 year) are variable. Further studies are therefore required. (Grade A, Level Ib)

NZGG (2002)	Encourage NRT except under exceptional circumstances. Discuss NRT with patients. Explain how these medicines increase smoking cessation success and decrease withdrawal symptoms.
	At the time of the publication of this guideline in 2002, NRT was available in New Zealand both over-the-counter at pharmacies and from the Quitline and authorized nicotine patch and gum providers. NRT in New Zealand is available as nicotine patches and gum (over- the-counter), nicotine nasal spray (prescription medicine), and nicotine inhaler (pharmacist only).
	NRT is effective for addicted smokers (more than 10 cigarettes per day) who are motivated to quit, especially when used as an adjunct to counselling/support with organised follow-up.
	Inform NRT users not to smoke at all while using NRT and provide with copy of relevant "information sheet."
	If previous failure or contraindication to NRT, discuss use of bupropion or nortriptyline.
	Combination Therapy
	Combination NRT appears to have the potential to provide effective treatment of tobacco dependence in people whose dependence is refractory to monotherapy with NRT. There is currently insufficient evidence to recommend the use of NRT with bupropion or nortriptyline in combination.
USPSTF (2003)	FDA-approved pharmacotherapy that has been identified as safe and effective for treating tobacco dependence includes several forms of NRT (i.e., nicotine gum, nicotine transdermal patches, nicotine inhaler, and nicotine nasal spray) and sustained-release bupropion. Other medications, including clonidine and nortriptyline, have been found to be efficacious and may be considered.
	Combination Therapy
	There are fair quality studies showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone.
VA/DoD (2004)	Tobacco users attempting to quit should be prescribed one or more effective first-line pharmacotherapies for tobacco use cessation. [A]
	First-line therapies include five NRTs (transdermal patch, gum, nasal spray, lozenges, or vapor inhaler) and non-nicotine replacement (bupropion immediate release [IR] or

- sustained release [SR]). [A]
- Pharmacotherapy should be combined with minimal counseling (less than 3 minutes). [A]
- Patient should be strongly advised not to use tobacco while using NRT.
- Selection of an agent should be based on patient characteristics, relative contraindications, and patient preferences. [Expert Consensus]
- Typical duration for NRT is 8 to 12 weeks, and for bupropion
   7 to 12 weeks [Expert Consensus]

Tobacco users who do not respond to first-line therapies should:

- Continue the same agent for a longer duration
- Switch to a different first-line agent or
- Consider combination of two agents.

## Combination Therapy

Combination therapy may be effective for patients unable to quit with a single first-line agent. [B]

- Combining the nicotine patch with a self-administered form of NRT (gum or nasal spray) is more efficacious than a single form of NRT. [B]
- There is some suggestive evidence for combining bupropion SR with NRT, but it is inconclusive. [B]

#### Note:

- Pharmacotherapies NOT recommended for tobacco cessation: antidepressants other than bupropion SR and nortriptyline; anxiolytics/benzodiazepines/beta-blockers; silver acetate; and mecamylamine.
- Patient who responded to therapy and successfully quit the use of tobacco and then relapsed should be treated in same manner as the initial therapy.
- Insufficient evidence exists to recommend the use of extended pharmacotherapy for relapse prevention. [1]

## CONSIDERATIONS IN SPECIAL POPULATIONS

Pregnancy and Second-hand Smoke Exposure in Infants and Children

## UMHS (2001)

Intensive counseling interventions increase quit rates during pregnancy [A]. If intensive counseling is not possible, brief inoffice counseling still has a beneficial effect and should be offered. No studies have addressed the safety of nicotine replacement therapy or bupropion hydrochloride in pregnancy.

## SINGAPORE MOH (2002)

## **Drug Therapy During Pregnancy**

- Previous animal studies had associated nicotine with fetal neural abnormalities.
- Nicotine had also been shown to affect uteroplacental circulation and could contribute to fetal hypoxia. (Benowitz, 1991)
- On the other hand, serum nicotine levels are higher in active smokers compared to those receiving NRT.
- The efficacy of smoking cessation pharmacotherapy in pregnancy has not been tested. Also, its effect on pregnancy is unknown.
- As there is lack of data in pregnancy, it must be used with great caution. Pregnant smokers should be encouraged to stop smoking and psychosocial interventions should be used if necessary. If this fails, physicians may consider pharmacotherapy on an individual basis, after risk and benefit of such a therapy has been discussed with the patient. (Fiore et al., 2000) Grade C, Level IV

## NZGG (2002)

- Encourage pregnant women who smoke to quit, and those who have quit to remain non-smokers after delivery.
- Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective smoking cessation interventions to pregnant women at their prenatal visit as well as throughout their course of pregnancy.
- Give the free QUITLINE number (0800 778 778 in New Zealand), contact details of free services for pregnant women, Aukati Kai Paipa Smoking Cessation Services and NRT Exchange Card Providers in their locality.
- Self-help manuals have been shown to be helpful in this group.
- Most pregnant women who quit smoking while pregnant begin again after delivery—intervene with new parents often. Discuss nicotine delivery through breast milk.
- NRT should be considered when a pregnant/lactating woman is unable to quit, and when the likelihood of quitting, with its potential benefits, outweighs the risks of NRT and potential continued smoking. Keep in mind that the risks for the mother and fetus associated with smoking are greater than those associated with NRT use.
- Ask caregivers and parents about exposure to second-hand smoke at Well Child visits, and give parents smoking cessation advice. Discuss the relationship of second-hand smoke to illness at potentially related acute care visits, such as asthma, otitis media, and bronchiolitis.

## USPSTF (2003)

The USPSTF strongly recommends that clinicians screen all pregnant women for tobacco use and provide augmented pregnancy-tailored counseling to those who smoke (A recommendation).

The USPSTF found good evidence that extended or augmented smoking cessation counseling (5-15 minutes) using messages and self-help materials tailored for pregnant smokers, compared with brief generic counseling interventions alone, substantially increases abstinence rates during pregnancy, and leads to increased birth weights. Although relapse rates are high in the post-partum period, the USPSTF concluded that reducing smoking during pregnancy is likely to have substantial health benefits both for the baby and the expectant mother. The USPSTF concluded that the benefits of smoking cessation counseling outweigh any potential harms.

There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking.

## VA/DoD (2004)

The guideline refers to recommendations offered in <u>DoD/VA</u> <u>Clinical Practice Guideline for Management of Uncomplicated</u> <u>Pregnancy</u> regarding smoking cessation and pregnancy. Specific recommendations from this guideline include:

- Strongly recommend routine screening for tobacco use in pregnancy at the initial prenatal visit. For patients who smoke, recommend assessment of smoking status at each subsequent prenatal visit.
- If the screening is positive, cessation should be strongly recommended.
- There is insufficient data to recommend for or against pharmacologic therapy for tobacco cessation in pregnancy.

Background. Smoking in pregnancy presents risks for both the woman and the fetus. Tobacco use by pregnant women has been shown to cause adverse fetal outcomes, including stillbirths, spontaneous abortions, decreased fetal growth, premature births, low birth weight, placental abruption, sudden infant death syndrome (SIDS), cleft palates and cleft lips, and childhood cancers. Many women are motivated to quit during pregnancy, and health care professionals can take advantage of this motivation by reinforcing the knowledge that cessation will reduce health risks to the fetus and that there are postpartum benefits for both the mother and child. Even women who have maintained total abstinence from tobacco for 6 or more months during pregnancy have a high rate of relapse in the postpartum

	period. Postpartum relapse may be decreased by continued emphasis on the relationship between maternal smoking and poor health outcomes in infants and children (i.e., SIDS, respiratory infections, asthma, and middle ear disease).
Children and	Adolescents: Screening and Prevention of Initiation of Smoking
UMHS (2001)	No recommendations offered.
SINGAPORE MOH (2002)	No recommendations offered.
NZGG (2002)	Ask children over the age of 10, "Have you ever smoked a cigarette?"
	POSITIVELY REINFORCE non-smoking, particularly with adolescents.
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (I recommendation).
	The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use.
VA/DoD (2004)	Pediatric and adolescent patients and their parents should be screened by health care providers for tobacco use and provided a strong message regarding the importance of total abstinence from tobacco use. [Expert Consensus]
	Health care providers in a pediatric setting should advise parents to quit smoking to limit their children's exposure to second-hand smoke. [A]
	Health care providers in a pediatric setting should offer smoking cessation advice and interventions to parents to improve the parent's chance of quitting use of tobacco. [C]
Children and Adolescents: Counseling and Treatment of Tobacco- dependence	
UMHS (2001)	The treatment strategies described above for adults will apply to most adolescents who smoke. Clinicians should personalize the encounter to the individual adolescent's situation. NRT may be considered. Bupropion has been studied only in adults.

SINGAPORE MOH (2002)	No recommendations offered.
NZGG (2002)	No cessation programme for teen smokers has been shown to work, so prevention is the key (e.g., repeated positive reinforcement of abstinence).
	Counselling and behavioural interventions shown to be effective with adults should be considered for use with children and adolescents. The content of these interventions should be modified to be developmentally appropriate.
USPSTF (2003)	The USPSTF concludes that the evidence is insufficient to recommend for or against routine screening for tobacco use or interventions to prevent and treat tobacco use and dependence among children or adolescents (I recommendation).
	The USPSTF found limited evidence that screening and counseling children and adolescents in the primary care setting are effective in either preventing initiation or promoting cessation of tobacco use. The USPSTF found that school- and classroombased smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates.
	There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.
VA/DoD (2004)	Adolescents who use tobacco and are interested in quitting should be offered counseling and behavioral interventions that were developed for adolescents. [A]
	Counseling and behavioral interventions shown to be effective with adults may be considered for use with adolescents. [Expert Consensus]
	When treating adolescents, providers may consider prescriptions for bupropion SR or NRT when there is evidence of nicotine dependence and desire to quit tobacco use. [Expert Consensus]
	oncerns, Racial/Ethnic Minorities, Patients with Psychiatric ofactors, Older Smokers, and Hospitalized Patients
UMHS (2001)	Gender Concerns

Smoking cessation treatments are shown to benefit both women and men [B]. Two studies suggest that some treatments are less efficacious in women than in men. Women may face different stressors and barriers to quitting (e.g., greater likelihood of depression, greater weight control concerns, and hormonal cycle). This research suggests cessation programs that address these issues would be more effective in treating women [D].
Racial/Ethnic Minorities
Smoking cessation treatment has been shown to be effective across both racial and ethnic minorities [A]. Little research has examined intervention specifically designed for a particular ethnic or racial group; however, it is recommended that, when possible, smoking cessation treatment should be tailored to the specific ethnic or racial population with which they are used [C].
Psychiatric Cofactors
If presence of psychiatric cofactors, such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse, strongly consider referral to intensive counseling [B]. Treatment of cofactors must be undertaken in preparation for smoking cessation.
Older Smokers
Smoking cessation treatment has been shown to be effective for older adults and should be provided [A]. Due to particular concerns of this population (e.g., mobility issues) the use of proactive telephone counseling appears to be promising as a treatment modality.
Hospitalized Smokers
A few studies comparing augmented smoking cessation with usual care of hospitalized patients suggest smoking cessation treatment to be effective [B]. Hospitalization should be used as a springboard to promote smoking cessation.
No recommendations offered.
Maori  Maori are more likely to be in an environment with other smokers, which may make quitting more difficult. International evidence demonstrates that quit support initiatives have been less successful among lower socioeconomic groups. There are a

number of kaupapa Maori cessation services that provide Maori with excellent support (e.g., Aukati Kai Paipa and Noho Marae). Consider referral to culturally appropriate providers where possible. The QUITLINE (0800 778 778 in New Zealand) provides Maori advisors. Also consider providing contact details of Aukati Kai Paipa and other Maori smoking cessation services and NRT Exchange Card Providers in their area.
Smokers with Mental Health Problems
Smokers should be asked about mental health problems and other chemical use, and referred to counsellors, mental health services, or drug and alcohol services if indicated, in addition to being encouraged to quit. Smokers with mental health problems should be provided with effective smoking cessation treatments. Evidence indicates that smoking cessation interventions do not interfere with recovery from chemical dependency. Therefore, smokers receiving treatment for chemical dependency should be provided with effective smoking cessation treatments, including both counselling and pharmacotherapy.
Hospitalised Smokers
A hospitalisation provides a powerful opportunity to quit. Hospitalised patients are forced to cut down or quit and may be more motivated to remain so after discharge. Consider prescribing NRT during hospital stay.
No recommendations offered.
Military Recruits and Trainees
Prevent relapse of basic trainees who quit using tobacco as a result of their participation in basic military training.
Relapse prevention should be addressed with every former tobacco user. [Expert Consensus]
Hospitalized Patients
Encourage all health care team members to advise hospitalized tobacco users to quit and provide tobacco cessation treatment.
<ul> <li>All patients admitted to hospitals should have tobacco use status identified in the medical record. [A]</li> <li>Tobacco users who are hospitalized should be given advice to quit. [B]</li> <li>Tobacco users who are hospitalized should be given tobacco cessation treatment including medication and counseling.</li> </ul>

[B

- Whenever possible, augmented smoking cessation treatment should be provided to tobacco users who are hospitalized. [Expert Consensus]
- Tobacco users should be referred for continuing treatment and support upon discharge. [Expert Consensus]

#### Older Patients

Encourage all health care team members to advise older tobacco users to guit and provide tobacco cessation treatment.

- Tobacco users who are older should be given advice to quit.
   [A]
- Tobacco users who are older should be given tobacco cessation treatment, including medication and counseling.
- There are insufficient data to support or refute variations on smoking cessation interventions among the elderly.
   Assessment and treatment of tobacco users who are older should follow the recommendations included in the guideline.
   [1]

## Psychiatric/Mental Health Patient

Provide effective tobacco cessation services to patients with psychiatric comorbidities

- Tobacco users with comorbid psychiatric and substance abuse conditions should be provided tobacco cessation treatment. [B]
- Tobacco users receiving treatment for chemical dependency should be provided tobacco cessation treatments to include counseling and pharmacotherapy. [C]
- Tobacco users with other comorbidities may have a low rate of successful treatment. The optimal treatment for tobacco users with current/past depression is uncertain, but they may require longer and more intensive treatment. [B]

TABLE 3: BENEFITS AND HARMS	
	POTENTIAL BENEFITS
UMHS (2001)	Effective interventions and strategies are provided that could help health care providers assist patients in smoking cessation.

## SINGAPORE MOH (2002)

- It is beneficial to stop smoking at any age as it has major and immediate health benefits even for smokers who have smoked for many years. Within two days of quitting, the sensations of smell and taste are enhanced. Within two weeks to three months of quitting, circulation improves and lung function increases by up to 30%. The excess risk of heart disease is reduced by half within one year of stopping smoking. Within five years, the risk of heart disease reduces to the level of non-smokers. In those with existing heart disease, smoking cessation reduces the risk of recurrent infarction or death by half. The risk of lung cancer is reduced by 50 to 70% after 10 years of abstinence from smoking and continues to decline thereafter.
- Women who stop smoking before or during the first trimester of pregnancy reduce the risk to their baby to a level comparable to that of women who have never smoked. The incidence of babies born with low birth weight could potentially be reduced by 25% if pregnant women do not smoke during pregnancy.

## NZGG (2002)

- It is beneficial to stop smoking at any age. The earlier smoking is stopped, the greater the health gain.
- Smoking cessation has major and immediate health benefits for smokers of all ages. Former smokers have fewer days of illness, fewer health complaints, and view themselves as healthier.
- Within one day of quitting, the chance of a heart attack decreases.
- Within two days of quitting, smell and taste are enhanced.
- Within two weeks to three months of quitting, circulation improves and lung function increases by up to 30 percent.
- Excess risk of heart disease is reduced by half after one year's abstinence. The risk of a major coronary event reduces to the level of a never smoker within five years. In those with existing heart disease, cessation reduces the risk of recurrent infarction or death by half.
- Former smokers live longer: after 10 to 15 years' abstinence, the risk of dying almost returns to that of people who never smoked. Smoking cessation at all ages, including in older people, reduces risk of premature death.
- Men who smoke are 17 times more likely than non-smokers to develop lung cancer. After 10 years' abstinence, former smokers' risk is only 30 to 50 percent that of continuing smokers, and continues to decline.
- Women who stop smoking before or during the first trimester of pregnancy reduce risks to their baby to a level comparable to that of women who have never smoked. Around one in four low birth weight infants could be prevented by eliminating smoking during pregnancy.
- The average weight gain of three kg and the adverse

	temporary psychological effects of quitting are far outweighed by the health benefits.
USPSTF (2003)	Smoking Cessation Benefits
(====)	There is good quality evidence that smoking cessation lowers the risk for heart disease, stroke, and lung disease.
	Effectiveness of Counseling
	The USPSTF found good quality evidence examining the efficacy of various levels of intensity of tobacco cessation counseling by clinicians based on a meta-analysis of 43 studies. Compared with no intervention, minimal counseling, lasting less than 3 minutes, has been shown to increase overall tobacco abstinence rates. Increasing session length and frequency increased efficacy in a dose-response manner. There is limited evidence to determine the optimal duration and periodicity of tobacco counseling interventions.
	Pregnancy-tailored Counseling
	A meta-analysis of 7 studies found that abstinence rates were higher (16.8% vs. 6.6%) for pregnant smokers receiving pregnancy-tailored counseling and self-help materials compared with pregnant smokers receiving brief counseling or "usual care."
	Counseling for Children/Adolescents
	The USPSTF found limited evidence of the efficacy of counseling children or adolescents in the clinical primary care setting, but found that school- and classroom-based smoking cessation programs may be more effective than no intervention among tobacco users who attend these programs. As with tobacco cessation programs for adults in the community setting, programs with a greater number of counseling sessions and increasing intensity of follow-up had higher quit rates.
	Effectiveness of Pharmacotherapy
	Several FDA-approved pharmacotherapies have been identified as safe and effective in helping adults to quit smoking.
	<ul> <li>Nicotine products, including nicotine gum, transdermal patch, nicotine nasal spray, and nicotine inhaler, have all been studied in comparison with placebo. There are good quality studies to support the abstinence rates among people who use these products compared with those who do not: 18 to 31% versus 10 to 17%. There are fair quality studies</li> </ul>

- showing that combining the nicotine patch with either the gum or nasal spray is more efficacious than using a single form of nicotine replacement therapy alone.
- Sustained-release bupropion has been shown to be efficacious compared with placebo, with an estimated cessation rate of 23 to 38% compared with 17%.
- Other pharmacotherapies, including clonidine and nortriptyline, have been shown to result in higher smoking cessation rates when compared with placebo, although their use may be limited by side effects.

## VA/DoD (2004)

- Early detection of tobacco use
- Decreased rates of tobacco use
- Increased rates of smoking cessation
- Prevention of tobacco use in students who have not starting using tobacco
- Decreased rates of relapse in persons who have quit tobacco use
- Flexibility to accommodate local policies or procedures, including those regarding staffing patterns and referral to or consultation with other health care providers.
- Appropriate management of tobacco use in target population
- Improved patient education regarding abstinence from tobacco

#### Subgroups Most Likely to Benefit

There are special target populations of smokers who need to be identified and referred for intervention because of the high likelihood of adverse outcomes that accompany continued tobacco use. These include:

- Pregnancy Due to increased risk to the mother and potential fetal prematurity, all pregnant patients should be encouraged to stop smoking as early in pregnancy as possible.
- Chronic tobacco related disease Smokers who have developed a progressive, chronic tobacco related disease (emphysema, coronary artery disease, peripheral vascular disease) that will continue to deteriorate should be urged to make an attempt to quit tobacco during routine primary care for those disorders.
- Complications of surgical anesthesia Smoking cessation should be addressed with all pre-operative patients. If tobacco users will quit smoking 4 to 6 weeks prior to anesthesia, complications and postoperative recovery (infections, wound healing, cardiac procedures) can be reduced.

	POTENTI AL HARMS
UMHS (2001)	<ul> <li>Side effects of medications may occur and include the following:</li> <li>Transdermal nicotine patch. Skin reactions such as pruritus, edema, rash; sleep disturbance</li> <li>Nicotine gum (polacrilex). Jaw fatigue, hiccups, belching, and nausea</li> <li>Nicotine nasal spray. Nasal irritation/rhinorrhea (98% of patients), sneeze, cough. Severity of effects decrease after first week.</li> <li>Nicotine inhaler. Cough, mouth and throat irritation</li> <li>Bupropion hydrochloride SR (Zyban). Insomnia and dry mouth</li> <li>Clonidine. Dry mouth and sedation</li> <li>Nortriptyline. Dry mouth</li> <li>No studies have addressed the safety of nicotine replacement therapy or bupropion hydrochloride in pregnancy. The FDA pregnancy risk categories are: Zyban — category B, nicotine transdermal, spray and inhaler — category D, nicotine gum — category C.</li> <li>Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.</li> </ul>
SINGAPORE MOH (2002)	Nicotine Patch: Skin irritation such as itch and rash caused by direct contact is the most common side effect. Other side effects include nausea, vomiting, headache, insomnia, and nightmares.  Nicotine Inhaler: Main side effects are irritation in the mouth and throat and coughing. Other uncommon side effects listed in the product insert include nausea, vomiting, heartburn, nasal congestion, sinusitis, headache, and dizziness.  Bupropion Hydrochloride Slow-Release: Adverse drug reactions reported to the Canadian Adverse Drug Reaction Monitoring Program (CADRMP) included myocardial infarction, seizures, hypoglycaemia, allergic reactions, nausea, anxiety, insomnia, and dizziness.

# NZGG Smoking Cessation: Weight gain (2002)

Nicotine Replacement Therapy (NRT): After overdose, upset stomach/abdominal pain, nausea/vomiting, diarrhoea, dizziness, tachycardia, change in hearing/vision, bad headache, flushing, confusion, and hypotension may occur. Withdrawal symptoms (underdose) include craving, irritability, anxiety, sleep disturbance, impaired concentration, hunger, weight gain, and

depression. Dependence can also occur.

Manufacturers' information states that nicotine passes to the fetus and affects its breathing movements and circulation, and that nicotine passes freely into breast milk in quantities that may affect the child even with therapeutic doses and that ideally nicotine should be avoided during breast-feeding.

Bupropion: Seizures, drowsiness, loss of consciousness, and other undesirable effects can occur. The safety and efficacy of bupropion for patients under 18 years of age or for use in pregnancy has not been established.

Nortriptyline: Sometimes causes sedation, constipation, urinary retention, and cardiac problems and when taken as an overdose could be fatal. The most common side effect in trials was dry mouth.

## USPSTF (2003)

There is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweighs the risks of the therapy and continued smoking. Likewise, there is little evidence on the safety and efficacy of tobacco cessation pharmacotherapy in children or adolescents.

## VA/DoD (2004)

#### Adverse Effects of Medication

- Nicotine Transdermal (patch): sleep disturbance, local irritation, bone pain, headache, nausea
- Nicotine Polacrilex Resin (gum): local mouth irritation, jaw pain, rhinitis, nausea
- Nicotine Polacrilex Resin (lozenge): local mouth irritation, headache, nausea, diarrhea, flatulence, hiccup, heartburn, cough
- Nicotine Nasal Spray: headache, nausea, confusion, palpitations, nasal irritation
- Nicotine Oral Vapor Inhaler: local irritation, cough, rhinitis, headache, dyspepsia
- Bupropion Sustained Release (SR) and Bupropion Immediate Release (IR): anxiety, disturbed concentration, dizziness, insomnia, constipation, dry mouth, nausea
- Clonidine and nortriptyline are associated with more severe adverse effects (significant drug-drug interactions) than either NRT or bupropion SR. Withdrawal effects from abrupt discontinuation can also be serious. These agents should be used only under the supervision of a physician.

#### Subgroups Most Likely to Be Harmed

- Use of NRT must be carefully assessed and monitored in persons with hyperthyroidism, peptic ulcer disease, insulindependent diabetes mellitus, temporomandibular joint (TMJ) syndrome (nicotine gum), severe renal impairment, and certain peripheral vascular diseases.
- Nicotine from any NRT product may be harmful to children and pets if taken orally.

#### TABLE 4. EVI DENCE RATING SCHEMES AND REFERENCES

## UMHS (2001)

Levels of evidence reflect the best available literature in support of an intervention or test:

- A. Randomized controlled trials
- B. Controlled trials, no randomization
- C. Observational trials
- D. Opinion of expert panel

## SINGAPORE MOH (2002)

#### **Grades of Recommendation**

Grade A (evidence levels Ia, Ib) Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation

Grade B (evidence levels IIa, IIb, III) Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation

Grade C (evidence level IV) Requires evidence obtained from expert committee reports of opinions and/or clinical experiences of respected authorities. Indicates absence of directly applicable clinical studies of good quality

GPP (good practice points) Recommended best practice based on the clinical experience of the guideline development group

#### Levels of Evidence

La Evidence obtained from meta-analysis of randomised controlled trials

I b Evidence obtained from at least one randomised controlled trial

II a Evidence obtained from at least one well-designed controlled study without randomisation

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

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NZGG (2002)	Rating Scheme for the Strength of the Evidence  Evidence quality was graded using The US Preventive Services Task Force grading system.
	Evidence obtained from at least one properly randomised controlled trial (RCT)
	II-I  Evidence obtained from well-designed controlled trials without randomisation
	II-II  Evidence obtained from well-designed cohort or case-control
	analytic studies, preferably from more than one centre or research group  II-III
	Evidence obtained from multiple time series with or without intervention
	Opinions of respected authorities, based on clinical experience
	Definitions  The Task Force grades its recommendations according to one of 5 classifications (A, B, C, D, I) reflecting the strength of evidence and magnitude of net benefit (benefits minus harms):
	A  The USPSTF strongly recommends that clinicians provide [the service] to eligible patients. The USPSTF found good evidence that [the service] improves important health outcomes and concludes that benefits substantially outweigh harms.
	B

The USPSTF recommends that clinicians provide [this service] to eligible patients. The USPSTF found at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

C

The USPSTF makes no recommendation for or against routine provision of [the service]. The USPSTF found at least fair evidence that [the service] can improve health outcomes but concludes that the balance of benefits and harms is too close to justify a general recommendation.

D

The USPSTF recommends against routinely providing [the service] to asymptomatic patients. The USPSTF found at least fair evidence that [the service] is ineffective or that harms outweigh benefits.

Т

The USPSTF concludes that the evidence is insufficient to recommend for or against routinely providing [the service]. Evidence that [the service] is effective is lacking, of poor quality, or conflicting and the balance of benefits and harms cannot be determined.

The USPSTF grades the quality of the overall evidence for a service on a 3-point scale (good, fair, poor):

#### Good

Evidence includes consistent results from well-designed, well-conducted studies in representative populations that directly assess effects on health outcomes.

#### Fair

Evidence is sufficient to determine effects on health outcomes, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies, generalizability to routine practice, or indirect nature of the evidence on health outcomes.

#### Poor

Evidence is insufficient to assess the effects on health outcomes because of limited number or power of studies, important flaws in their design or conduct, gaps in the chain of evidence, or lack

	of information on important health outcomes.
VA/DoD (2004)	Quality of Evidence (QE)
	I: Evidence obtained from at least one properly randomized controlled trial
	II-1: Evidence obtained from well-designed controlled trails without randomization
	II-2: Evidence obtained from well-designed cohort or case- control analytic studies
	II-3: Evidence obtained from multiple time series, dramatic results in uncontrolled experiments
	III: Opinions of respected authorities; case reports, and report of expert committees
	Overall Quality
	Good: High grade evidence (I or II-1) directly linked to health outcome
	Fair: High grade evidence (I or II-1) linked to intermediate outcome or Moderate grade evidence (II-2 or II-3) directly linke to health outcome
	Poor: Level III evidence or no linkage of evidence to health outcome
	Net Effect of Intervention
	Substantial:
	<ul> <li>More than a small relative impact on a frequent condition with a substantial burden of suffering, or</li> <li>A large impact on an infrequent condition with a significant impact on the individual patient level</li> </ul>
	Moderate:
	<ul> <li>A small relative impact on a frequent condition with a substantial burden of suffering, or</li> <li>A moderate impact on an infrequent condition with a significant impact on the individual patient level</li> </ul>
	Small:

- A negligible relative impact on a frequent condition with a substantial burden of suffering, or
- A small impact on an infrequent condition with a significant impact on the individual patient level

#### Zero or Negative:

- · Negative impact on patients, or
- No relative impact on either a frequent condition with a substantial burden of suffering, or
- An infrequent condition with a significant impact on the individual patient level

#### Grade of Recommendation

A: A strong recommendation that the intervention is always indicated and acceptable

B: A recommendation that the intervention may be useful/effective

C: A recommendation that the intervention be considered

D: A recommendation that a procedure may be considered not useful/effective, or may be harmful

I: Insufficient evidence to recommend for or against; the clinician will use clinical judgment

#### **GUI DELI NE CONTENT COMPARI SON**

The University of Michigan Health System (UMHS), Singapore Ministry of Health (MOH), New Zealand Guideline Group (NZGG), United States Preventive Services Task Force (USPSTF), and Department of Veterans Affairs, Department of Defense (VA/DoD) present recommendations for tobacco use cessation and prevention. The organizations provide explicit reasoning behind their judgments and rate the evidence upon which their recommendations are based.

All of the guidelines included in this synthesis utilized to some degree, evidence and recommendations released in 2000 by the U.S Public Health Service (PHS). For instance, UMHS utilized evidence derived from literature searches of both the 1996 Agency for Health Care Policy and Research (now the Agency for Healthcare Research and Quality [AHRQ]) guideline and the 2000 PHS guideline (both of which are now considered out of date). UMHS also supplemented the supporting evidence for their recommendations with subsequently published information. USPSTF likewise based its recommendations on the evidence provided in the 2000 PHS document including more recently published literature. NZGG frequently compares its recommendations with those of PHS; Singapore MOH also cites the

PHS guideline as a reference in its guideline. The VA/DoD guideline refers often to the PHS guideline but has also based its recommendations on an extensive review of more recent literature.

Although all groups provide recommendations on identification of tobacco users and the benefits of counseling and adjunctive pharmacologic treatment for tobacco use, VA/DoD provides the most extensive and comprehensive review, presenting detailed outlines for both brief and intensive strategies to be used by clinicians for tobacco use intervention. NZGG likewise, provides smoking cessation training information for health professionals. VA/DoD also emphasizes a "Population Health" strategy that promotes primary-care based treatment and prevention.

## Areas of Agreement

The recommendations for tobacco use cessation and prevention are in almost total concurrence for all five guideline groups. The "Five A" behavioral counseling framework of asking (identifying users), advising (urging users to quit), assessing (determining users' willingness to quit), assisting (through counseling or drug therapy), and arranging for follow-up is universally recommended. NZGG deviates slightly from this approach by "assessing" patients' willingness to quit before offering "advice".

#### Identification and Documentation of Tobacco Users

The guidelines are in general agreement regarding the need to identify tobacco users during routine clinic visits. Most groups recommend the use of a chart or sticker system to label a patient as a user or former user of tobacco.

#### Benefits of Counseling

All of the guidelines agree on the effectiveness of counseling as a means for clinicians to modify behavior and address tobacco dependence in their patients. All guidelines agree that advice to patients should be "clear," "strong," and "personalized" and should include a discussion of the health benefits of quitting, self-help materials, and referral to community groups, if necessary. Each of the guidelines also agrees that patients who do not wish to quit should receive motivational interventions (e.g., the 5 R's: relevance, risks, rewards, roadblocks, and repetition). The importance of frequent and/or intensive counseling is also stressed by all of the organizations. In particular, the dose-response relationship between treatment intensity and abstinence from tobacco use is emphasized.

#### Adjunctive Pharmacologic Therapy

The use of nicotine replacement therapy (NRT) as an adjunct to counseling is endorsed by all five guideline groups, except in special circumstances. Bupropion is also recommended by all groups as either first-line or second-line medication. Nortriptyline is recognized as a second-line treatment by all five groups. The use of clonidine as second-line therapy is discussed under "areas of differences" below.

There is also general agreement between the groups with respect to the efficacy of combination NRT. UMHS, NZGG, Singapore MOH, USPSTF, and VA/DoD note that studies with combination NRT suggest improved efficacy compared with single forms of NRT. UMHS, however, notes that, given the additional cost of dual therapies, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts.

There are some disagreements on the use of drug therapy in pregnant women and in children and adolescents, and these differences are also discussed below.

#### **Prevention Strategies**

The need for follow-up to prevent and treat relapses is acknowledged by UMHS, Singapore MOH, NZGG, and VA/DoD (USPSTF does not provide any specific recommendations in this area).

NZGG, and VA/DoD also emphasize the need for clinicians to help prevent the initiation of tobacco use in children and adolescents through direct counseling or by participation in school-based or community programs.

#### Passive Smoke Exposure

NZGG and VA/DoD offer specific recommendations on counseling to parents on the need to limit children's exposure to second-hand smoke. UMHS and VA/DoD state that the negative effects of passive smoking should be emphasized in trying to motivate smokers to quit.

Gender Concerns, Racial/Ethnic Minorities, Patients with Psychiatric Cofactors, Older Smokers, and Hospitalized Patients

UHMS, NZGG, and VA/DoD address special populations in their guidelines. All three groups agree that these special populations can benefit from many of the same treatments as the general population, but that treatment can be improved by recognizing the problems or concerns of the individual.

#### Areas of Differences

#### Adjunctive Pharmacologic Treatment

There are some differences among groups concerning use of clonidine as second-line treatment. UMHS and Singapore MOH recommend clonidine as a second-line treatment in patients unwilling or unable to use NRT or bupropion or who fail on first-line therapy. VA/DoD likewise state that clonidine may be considered on a case-by-case basis after first-line treatments have been used or considered, and should only be used under the supervision of a physician. USPSTF states that clonidine may be considered as pharmacotherapy because it results in higher smoking cessation rates when compared with placebo, although its use may be limited by side effects. NZGG, however, does not recommend clonidine even as second-line therapy because of the high incidence of side effects.

Counseling and Treatment of Children and Adolescents

The four groups that provide specific recommendations on counseling and treatment of child and adolescent tobacco users differ somewhat in their approach. VA/DoD states that adolescents who use tobacco and are interested in quitting should be offered counseling and behavioral interventions that were developed for adolescents. They note however that interventions shown to be effective with adults may also be considered with adolescents.

VA/DoD recommends adjunctive pharmacotherapy but only when the clinician has evidence that the adolescent is nicotine dependent and is willing to quit. UMHS states that the same counseling and treatment strategies used in adults can be applied to adolescents; however, clinicians should personalize treatment to the individual adolescent. Both NZGG and USPSTF, however, state that there is no evidence for the efficacy of cessation programs in young people. USPSTF therefore does not recommend for or against any routine interventions in the primary care setting for screening or treatment of children or adolescents for tobacco use. NZGG states that because of the limited success of cessation programs in children and adolescents, prevention should be emphasized; however, if counseling and behavioral interventions are used, these interventions should be developmentally appropriate.

## Treatment During Pregnancy

Although all of the groups strongly endorse smoking cessation interventions in pregnant women who smoke, they differ in their recommendations concerning use of pharmacologic therapy. NZGG and Singapore MOH, recommend drug therapy "when the likelihood of guitting and its potential benefits outweigh the risks of the therapy and continued smoking." VA/DoD (through <u>DoD/VA Clinical Practice</u> Guideline for Management of Uncomplicated Pregnancy) and UMHS make no recommendations either for or against drug therapy during pregnancy, VA/DoD notes that there is insufficient data to recommend for or against pharmacologic therapy for tobacco cessation in pregnancy. UMHS's quideline states that the safety of NRT and bupropion have not been studied in pregnancy and they refer to the FDA pregnancy risk categories for these drug therapies. USPSTF also cites the lack of evidence on the safety and efficacy of pharmacotherapy for the pregnant woman, the fetus, or the nursing mother and child. Therefore, USPSTF makes no recommendations for or against pharmacotherapy during pregnancy, but advises that "pharmacotherapy for pregnant women may be considered when the likelihood of quitting and its potential benefits outweigh the risks of the therapy and continued smoking."

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